PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ogsiveo Prior Authorization Policy
- Ogsiveo™ (nirogacestat tablets – SpringWorks Therapeutics)

REVIEW DATE: 12/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Ogsiveo, a gamma secretase inhibitor, is indicated for **progressing desmoid tumors** that require systemic treatment in adults.[1]

Disease Overview

Desmoid tumors, or aggressive fibromatosis, are rare soft-tissue tumors.[2] These types of tumors are locally aggressive and invasive, leading to morbidity, but rarely mortality. Desmoid tumors are not metastatic tumors. The enlarged size of some of the tumors can lead to compression of vital structures, resulting in severe pain, functional impairment, nerve damage, and bowel obstruction or perforation. Pain is associated with disease progression and can lead to opioid dependence or suboptimal pain management due to the concern for opioid dependence. Surgery used to be the mainstay of treatment; however, due to high morbidity and postsurgical recurrence rates of up to 50% to 88%, it is used less frequently. Other treatments include

cytotoxic chemotherapy, tyrosine kinase inhibitors, local ablation, or radiation therapy.

Clinical Efficacy

The efficacy of Ogsiveo was assessed in a Phase III, double-blind, randomized, placebo-controlled trial in adults with progressing desmoid tumors not amenable to surgery.[1,2] Eligible patients (n = 142) were ≥ 18 years of age with a histologically confirmed diagnosis of progressing desmoid tumors, defined as ≥ 20% progression (according to Response Evaluation Criteria in Solid Tumors [RECIST], version 1.1) within 12 months before screening. Patients were randomized to receive Ogsiveo 150 mg or placebo orally twice daily until disease progression or unacceptable toxicity. Patients treated with Ogsiveo had a significant progression-free survival benefit over placebo. In the Ogsiveo group, 17% of patients had a progression event compared with 51% of patients in the placebo group (hazard ratio 0.29; 95% confidence interval: 0.15, 0.55; P < 0.001). The objective response rate was also significantly better in the Ogsiveo group compared with placebo: 41% vs. 8%, respectively (P < 0.001).

Guidelines

The National Comprehensive Cancer Network (NCCN) soft tissue sarcoma guidelines (version 1.2025 – May 2, 2025) recommend the following therapies as "Preferred" regimens for desmoid tumors (aggressive fibromatosis):[3] Ogsiveo (category 1), sorafenib (category 1), methotrexate and vinorelbine, methotrexate and vinblastine, imatinib, pazopanib, doxorubicin ± dacarbazine, and Doxil® (liposomal doxorubicin for intravenous injection) [except for Ogsiveo and sorafenib, all other agents listed are category 2A recommendations]. Sulindac or other nonsteroidal anti-inflammatory drugs, including celecoxib, are recommended for pain under "Useful in Certain Circumstances" (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ogsiveo. All approvals are provided for the duration noted below.

- **Ogsiveo™ (nirogacestat tablets - SpringWorks Therapeutics)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Desmoid Tumors (Aggressive Fibromatosis).** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** According to the prescriber, the patient has progressing desmoid tumors; AND
     Note: Progressing desmoid tumors are defined as ≥ 20% progression within 12 months.
   - **C)** The desmoid tumors are not amenable to surgery or radiotherapy; AND
   - **D)** According to the prescriber, the patient requires systemic treatment.

CONDITIONS NOT COVERED

- **Ogsiveo™ (nirogacestat tablets - SpringWorks Therapeutics) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

REFERENCES

1. Ogsiveo™ tablets [prescribing information]. Stamford, CT: SpringWorks Therapeutics; April 2024.
2. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-secretase inhibitor for desmoid tumors. *N Engl J Med*. 2023;388:898-912.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 1, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/29/2023
Selected Revision	**Desmoid Tumors (Aggressive Fibromatosis):** For criterion referring to desmoid tumors not amenable to surgery, added "or radiotherapy".	01/03/2024
Annual Revision	No criteria changes.	12/11/2024
Annual Revision	No criteria changes.	12/03/2025